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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,167	09/10/2003	Dahui Zhou	WYNC-0330/AM101206(NP)	3756
38791	7590	01/10/2006	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR PHILADELPHIA, PA 19103			KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 01/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/659,167

Applicant(s)

ZHOU ET AL.

Examiner

Joseph Kosack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 13, 26 and 30 is/are rejected.
- 7) ☒ Claim(s) 5, 12, and 14-25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/29/04 and 3/8/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-30 are pending in the instant application.

#### ***Amendments***

The amendment filed on November 21, 2005 has been acknowledged and entered in the record.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I (Claims 1-26 and 30) in the reply filed on November 21, 2005 is acknowledged. Further, an election of species has been made of the compound of Example 5, 2-[3-(5-Fluoro-1-methyl-1H-indol-3-ylmethyl)-azetidin-1-ylmethyl]-8-methyl-2,3-dihydro-[1,4]dioxino[2,3-f]quinoline, found on page 53, line 15 of the specification.

The traversal is on the ground(s) that the examination of all claims in a single application would not be unduly burdensome. This is not found persuasive because if the compound of Group I has been determined to be not novel and/or obvious, the search of a method of use would require a different search than that of the compound itself and impose a serious burden to the examiner.

The requirement is still deemed proper and is therefore made FINAL.

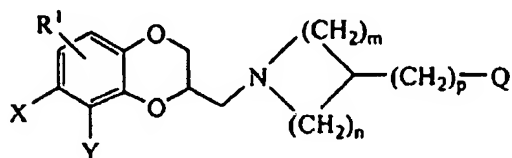
#### ***Status of the Claims***

Claims 1-30 are pending in the instant application. Claims 1-10 (in part), Claim 11, Claims 12-26 (in part), Claims 27-29, and Claim 30 (in part) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected

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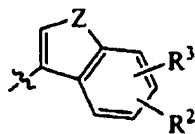
subject matter as it differs in the structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

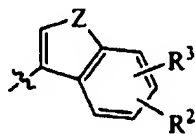
Pursuant to Applicant's election of a species, the scope of the invention will be limited to the following substitutions of the base structure



where:

- X and Y together will be  $-N=C(R^4)-C(R^6)=CH-$ ;



- Q will be  ;
- m, n, and p will be 1 or 2;
- R¹, R², R³, R⁴, R⁶, R⁹, and Z will be as defined.

As a result of the election and the corresponding scope of the invention defined supra, the remaining subject matter of Claims 1-10, 12-26, and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as indole, benzimidazole, quinoline, quinazoline, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 224(+) (diazines), class 546 subclass

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112(+) (quinolines), 548 subclass 452(+) (indoles), etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

### ***Priority***

The claims to priority of US Serial Number 60/410,168 filed on September 12, 2002 has been acknowledged in the instant application.

### ***Information Disclosure Statement***

The Information Disclosure Statements filed on January 29, 2004 and March 8, 2004 have been considered by the examiner. However, References 3, 5, 7, 9, 10, 15, and 18 on the Information Disclosure Statement filed on January 29, 2004 have not been considered in that they are not in compliance with MPEP 609 and 37 CFR 1.98 for failure to provide a copy of the publication or the portion of the publication which caused it to be listed. All other references cited have been considered fully by the examiner.

### ***Claim Objections***

Claims 1-10, 12-26, and 30 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

Applicant is advised that should claim 2 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

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one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

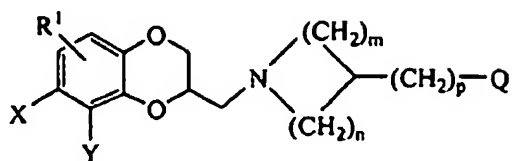
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

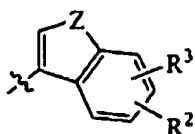
Claims 1-4, 6-10, 13, 26, and 30 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 32, and 42 of U.S. Patent No. 6,458,802 in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

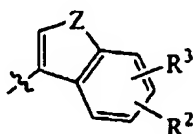
The instant application teaches a compound:

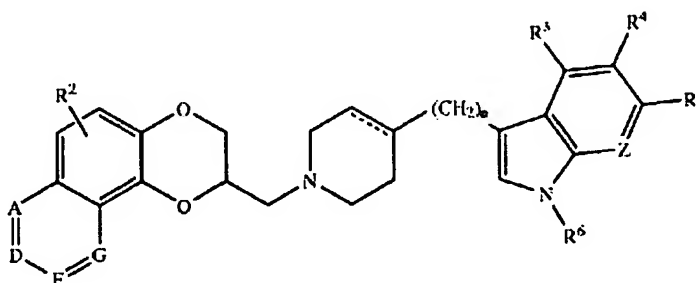
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where X and Y together is  $-N=C(R^4)-$



$C(R^6)=CH-$ ; Q is ; m, n, and p are either 1 or 2; and  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^6$ ,  $R^9$ , and Z are as defined; the S enantiomer substantially free of the R enantiomer; and a pharmaceutical composition comprising an effective amount of the above compound and a pharmaceutically acceptable carrier or excipient. Tran et al. teach a compound:



where A is nitrogen; D, E, and G are  $CR^1$ ; the dotted line is an optional double bond; n is 0-2; Z is  $CR^7$ ; and  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^5$ ,  $R^6$ ,  $R^7$  are as defined. Tran et al. also teaches the S enantiomer of the above compound substantially free of the R enantiomer. Tran et al. finally teach a pharmaceutical composition comprising an effective amount of the above compound and a pharmaceutically acceptable carrier or excipient. Tran et al. do not teach the use of an alkanoyl of 2 to 6 carbon atoms or an alkanesulfonyl of 1 to 6 carbon atoms at the  $R^2$ ,  $R^3$ ,  $R^4$ , or  $R^5$  positions corresponding to the  $R^1$ ,  $R^2$ , and  $R^3$  of the instant invention.

Patani et al. teach the bioisosteric replacement of an alkanamido with either an alkanoyl or an alkanesulfonyl. See page 3168, Figure 69 and Table 41.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to take the compound of Tran et al. and modify the R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, or R<sup>5</sup> positions using the bioisosteric replacements of Patani et al. with a reasonable expectation of success. The motivation to make the claimed compound derives from the expectation that structurally similar starting materials are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

### ***Conclusion***

Claims 1-4, 6-10, 13, 26, and 30 are rejected. Claims 1-10, 12-26, and 30 are objected to. Claims 5, 12, and 14-25 are free of the art.

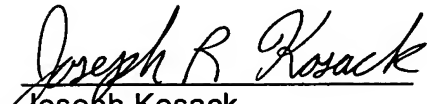
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:30-4:00.

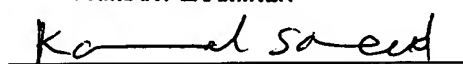
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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